



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,870	06/23/2000	John D Brennan	086671/0109	1416
22428	7590	12/08/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			DO, PENSEE T	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/599,870

Applicant(s)

BRENNAN ET AL.

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-27 and 39-65 is/are pending in the application.
- 4a) Of the above claim(s) 1-37 and 39-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Prosecution Re-opened

The advisory action sent out on October 26, 2004 is vacated herein because the new matter issue is withdrawn. Due to a new finding of prior art, the final office action sent on May 18, 2004 is also vacated and prosecution on this application is re-opened.

Withdrawn Rejection(s)

Rejection under 112, 1st paragraph in the final office action sent on May 18, 2004 is withdrawn herein.

New Grounds of Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 59 and 62-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 is indefinite for reciting "wherein the material" because the while the group of material comprises of inorganic material, the "material" referred to in claim 50 encompasses the organic, and inorganic material. It is suggested that —inorganic-- is added in front of "material".

Claim 62 is missing a word. The carrier "is" pre-treated?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 50, 51, 54, 55, 61-65, are rejected under 35 U.S.C. 102(e) as being anticipated by Kopetzki et al. (US 6,312,916).

Kopetzki teaches a test kit to qualitatively or/and quantitatively detect an analyte in a test sample which contains a polypeptide capable of binding to biotin as well as further components of the respective assay and an interference elimination reagent which comprises a mutein. The interference elimination reagent can be present in a soluble form or on a solid phase in particular on a microtitre plate, a microreagent vessel, and a membrane or immobilized on microbeads. The mutein is avidin and streptavidin in which at least one amino acid of the native polypeptide is substituted and which has a binding affinity to biotin as a system that can be regenerated for binding biotinylated substances. The solid phase on which the streptavidin muteins are immobilized can be sensor chips, reaction vessels such as polystyrene tubes or cuvettes, microtitre plates, microbeads, latex particles and support materials for affinity columns. Biotinylated substances are conjugates of biotin and biotin analogues, being those substance which form a complex with the biotin binding pocket of streptavidin or avidin. The solid phase can be used in assays for the detection of analytes, for the

Art Unit: 1641

investigation of receptor-ligand interactions and for the purification or analysis of biotinylated substances. On the other hand the binding affinity of the solid phase to biotin or a biotinylated substance is sufficiently low to enable a regeneration of the solid phase, i.e. it is possible to detach the biotin. The detachment is carried out by reducing the pH or/and by addition of chaotropic substances, i.e. substances which interfere with the formation of hydrogen bridges. Alternatively the detachment for isolating the biotinylated substances can also be achieved by adding free biotin or/and biotin analogues. (see col. 6, line 43-col. 7, line 50). Solid phase such as affinity columns inherently have pore size that inhibit leaching out of the biomolecular interaction or biological species thereof. The biological species of the biomolecular interaction can under naturing conditions associate with one another. The biomolecular interaction is bioactive. Regarding claims 62-65, because the limitations of these claims are drawn to a process of use or a process of making, they are not given any patentable weight.

Claims 50-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Babich et al. (US 6,395,299).

Babich teaches a sol-gel silica alkoxides matrix covalently attached to a biotin group and a reaction center attached to an avidin. The biotin/avidin interaction would effectively attach the reaction center to the silica oxide framework of any sol-gel matrix. An antibody/hapten pair could be used in the same fashion. The association of Biotin/avidin is a hydrogen bond. (see col. 29, lines 50-65). Pore size is an important characteristic of any sol-gel matrix, because it may affect what materials may diffuse in and out of the matrix, and the leachability of any encapsulated reaction center and/or

Art Unit: 1641

additives. The matrix of Babich contemplates pore sizes ranging from the angstrom level to the micron level depending on the material being encapsulated in the matrix. (col. 30, lines 35-44). The matrix uses a biotin/avidin interaction to attach a reaction center, i.e. enzyme such as L-amino acid decarboxylase to convert a prodrug such as L dopa to dopamine for treating Parkinson's disease. Thus, the matrix is implanted in the brain of a subject with Parkinson's disease. The dopamine must diffuse out of the matrix into the brain. (see col. 7, lines 11-34; col. 16, lines 51-65; col. 17, lines 43-58). Other oxides including metal oxides may be used to form the matrix. (see col. 30, lines 45-50). The matrix can be administered and remained in contact with a biological fluid, such as blood, internal organ secretions, mucus membranes, cerebrospinal fluid and the like. The length of the period during which the matrix remains active enough so as to produce a therapeutic effect may depend on a variety of features. Silica-based sol gel matrices can be active for periods of several months. (see col. 57, lines 24-35). Regarding claims 60, 62-65, because the limitations of these claims are drawn to a process of use or a process of making, they are not given any patentable weight.

Conclusion

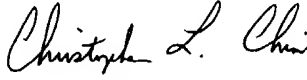
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
December 2, 2004


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641
12/2/04